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10/587,155

07/25/2006

Hyung-Kwon Lim

118.24-US-WO

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22462

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08/17/2009

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                   |  |
|------------------------------|--------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/587,155 | <b>Applicant(s)</b><br>LIM ET AL. |  |
|                              | <b>Examiner</b><br>MICHELE K. JOIKE  | <b>Art Unit</b><br>1636           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/25/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on April 30, 2009 is acknowledged. The traversal is on the ground(s) that there is no search burden. This is not found persuasive because showing a search burden is not required when breaking unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-18 are pending, with claims 6-18 withdrawn. Claims 1 and 3-5 are examined.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2007/0031379 in view of WO 03/100020, Brake et al (PNAS 81: 4642-4646, 1984), Lee et al, US 7,270,969 and Osborne et al.

US 2007/0031379 (especially paragraphs 54, 63, Ex. 1, Fig. 8 and SEQ ID NO: 2) teaches a vector comprising a promoter, a leader (which can be interpreted to mean a signal sequence), a LK8 cDNA sequence (SEQ ID NO: 2, which is the same sequence as SEQ ID NO: 1 in the current application), and a terminator, in that order. The vector can also contain a neomycin resistance gene. The vector can be transfected into a cell. However, the reference does not teach that the signal sequence is SEQ ID NO: 2, that the promoter is a GAL1 promoter, or that the terminator is a CYC1 terminator. It also does not teach use of a delta sequence.

Lee et al (Appl. Microbiol. Biotechnol. 48: 339-345, 1997, especially p. 339) disclose a delta-integration vector for the insertion of an inducible expression cassette and a bacterial neomycin resistance gene into the genome of *Saccharomyces cerevisiae* via homologous recombination; and a selection of the transformed cell containing integration by resistance to G418.

WO 03/100020 teaches SEQ ID NO: 24, which is an  $\alpha$ -factor secretion signal sequence (SEQ ID NO: 2 of the current application).

US 7,270,969 (especially column 36) teaches use of the GAL1 promoter in *S. cerevisiae*.

Osborne et al (PNAS 86: 4097-4101, 1989, especially pp, 4097 and 4101) teaches use of the CYC1 terminator in *S. cerevisiae*.

The ordinary skilled artisan, desiring to construct a vector with a GAL1 promoter, an alpha-factor secretion sequence, a LK8 cDNA, a CYC1 terminator, a neo marker and a delta sequence would have been motivated to combine the above teachings because US 2007/0031379 teaches a vector with a promoter, a secretion sequence, a LK8 cDNA, a terminator, and a neo marker, and US 7,270,969 teaches that the GAL1 promoter is a typical promoter suitable for expression in *S. cerevisiae*, and Brake et al teach that leader sequences allow for more efficient processing and secretion in yeast, and the alpha-factor efficiently secretes into the medium the mature biologically active protein, and Osborne et al teach that CYC1 acts as a terminator in *S. cerevisiae*, and is stable, with substitutions and deletions having little or no effect. Furthermore, Lee et al teach that direct integration into a host's genome is an effective way to introduce heterologous genes. It would have been obvious to one of ordinary skill in the art to make this vector because US 2007/0031379 teaches that LK8 gene showed anticancer effect by inhibiting the growth and the metastasis of a tumor, and inserting it into a vector is an effective means for delivery, and the other parts of the vector, for example the GAL1 promoter, are well-known in the art and would give predictable results when used. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled

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artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2007/0031379 in view of WO 03/100020, Brake et al, Lee et al, US 7,270,969 and Osborne et al as applied to claims 1 and 3 above, and further in view of Kumar et al.

US 2007/0031379, WO 03/100020, Brake et al Lee et al, US 7,270,969 and Osborne et al teach all of the limitations as described above. However, they do not teach the use of the *S. cerevisiae* strain, BY4742.

Kumar et al (Yeast 20:857-863, 2003, especially pp. 857-859 and Table 1) teach BY4742 transformed with a vector.

The ordinary skilled artisan, desiring to construct a vector with a GAL1 promoter, an alpha-factor secretion sequence, a LK8 cDNA, a CYC1 terminator, a neo marker and a delta sequence and transform it into BY4742 would have been motivated to combine the above teachings with Kumar et al because Kumar et al teach that BY4742 is a widely used strain. It would have been obvious to one of ordinary skill in the art to use BY4742 because Kumar et al teach that BY4742 is MAT $\alpha$ . Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

***Allowable Subject Matter***

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Examiner, Art Unit 1636

Michele K. Joike  
Examiner  
Art Unit 1636